REMARKS

Docket No.: 03108/0202224-US0

The specification has been amended to provide the priority information for this application, which is a national stage application under 35 U.S.C. §371 of PCT International Application No. PCT/IN03/00223, and further claims priority from Indian Patent Application No. 477/MAS/2002. Claims I-22 are pending. Claims 1, 3, 4 and 19-20 have been amended. Specifically, claims 1 and 19 have been amended to remove the recitations of "heterocyclyl" and the phrase "and its derivatives" (referring to derivatives of sulfonic acids) in the definition of variables R₁-R₁₂. This amendment reflects Applicants' election with traverse of the Group I claims for further prosecution. Claim 1 is directed to compounds of the formula (I) and claim 19 is directed to a process for making the compounds of formula (I). Claim 19 has been amended to more particularly recite the definitions of variables R₁-R₁₄ and n. Support for this amendment to claim 19 can be found in original claim 1. Claims 1-4 and 19-20 have been amended to conform the claim language to the requirements of U.S. patent law. Support for these amendments can be found in the claims as originally filed. No new matter has been added by way of these amendments.

The Examiner has required restriction because the application allegedly lacks unity of invention under PCT Rules 13.1 and 13.2. According to the Examiner, there is no unity of invention because the core structure of formula (I) is not a unifying criterion and the variables of formula (I) do not belong to a recognized class of chemical compounds. The Examiner asserts that the core structure of formula (I) is not a unifying criterion because it is not novel. The Examiner has exemplified seventeen groups into which the pending claims allegedly fall and has indicated that these groups are *exemplary* and therefore, the list of groups set forth in the Office Action is not exhaustive.

In response to the restriction requirement set forth in the Office Action, Applicants hereby provisionally elect with traverse Group I, claims 1-4 and 14, drawn to compounds with the variables as defined in the Office Action and compositions containing the compounds, for continued examination. Applicants further provisionally elect the compound 11-(2-N,N-

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dimethylaminoethyl)isoindolo[2,1-a]indol-6-one, which is exemplified in Example 1 and in which R_1 - R_{12} are hydrogen, R_{13} and R_{14} are methyl (e.g., $(C_1$ - C_3)alkyl), and n is 1.

At the outset, Applicants respectfully point out that the core structure common to all compounds set forth in the claims at issue is not "(1H-indol-1-yl)(phenyl)methanone," as alleged by the Examiner:

(1H-indol-1-vl)(phenvl)methanone

but rather the fused 4-ring structure isoindolo[2,1-a]indol-6-one:

isoindolo[2,1-a]indol-6-one.

Nevertheless, the Examiner's position is not well-taken because it confuses the "special technical feature" of Rule 13.2 with the "common structure" described in MPEP § 1850 III.B relating to Markush practice. There is a requirement that a special technical feature define a

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contribution over the prior art; there is <u>no</u> requirement that the "common structure" in Markush claims be novel.

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Under PCT Rule 13.2, unity of invention is satisfied when there is a "special technical feature" that defines a contribution that each invention, considered as a whole, makes over the prior art. In the special case of "Markush" claims, a special technical feature is present "when the alternatives are of a similar nature." M.P.E.P. VIII, Revision No. 5, § 1850 III.B. Alternatives are of a similar nature when "(A) all alternatives have a common property or activity; and (B)(1) a common structure is present ...; or (B)(2) ... all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains. *Id.* Contrary to the Examiner's contention, it is not necessary that the "common structure" be novel.

The Examiner's attention is directed to the PCT International Search and Preliminary Examination Guidelines, pages 84-88, attached hereto at Exhibit A. Example 18 depicts indole compounds with various substituents at R¹-R⁴ that are useful as pharmaceuticals. See Guidelines, page 84. According to the Guidelines, the indolyl moiety "is the significant structural element that is shared by all of the alternatives." Id. Although the indolyl moiety is not novel, the International Bureau of WIPO and the International Searching and Preliminary Examining Authorities found that unity of invention was present because all of the compounds in the recited group were alleged to possess the same utility. Id.

In the present case, a special technical feature is present because: (1) the compounds share a common structure – the isoindolo[1,2-a]indol-6-one core; and (2) all compounds encompassed by the Markush group are within the same recognized class of chemical compounds – isoindolo[1,2-1]indol-6-ones. Furthermore, the claimed compounds are believed to have the same utility, i.e., 5-HT receptor affinity and modulation of 5-HT activity.

The Examiner has failed to provide any evidence that the special technical feature does not define a contribution that each invention, considered as a whole, makes over the prior art. The only reference cited by the Examiner pertains to 1H-indol-1-yl(phenyl)methanone, which as

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discussed above is not the common structure of the claimed compounds, let alone the special technical feature. The International Search Report identifies a single reference (Dinnell et al., Bioorg. Med. Chem. Lett. 2001, 11(9):1237-1240) as affecting the novelty or inventive step of claim 1. However, the cited compound

NR₂ = 1-(2-Methoxyphonyf)piperazine.

does not read on the compounds of formula (I) because neither R¹¹ nor R¹² can be the oxygen in a carbonyl group. The Examiner has not documented any conclusion that the claimed compounds would be obvious over this reference. Accordingly, the novel arrangement of the compounds presently claimed represents a special technical feature that defines a contribution over the prior at.

Therefore, there is unity of invention among claims 1-22 and Applicants respectfully request rejoinder of all claims.

Applicants also note that all of the allegedly separate inventions identified by the Examiner "involve" the "same or corresponding special technical feature," in that they all rely on compounds having the isoindolo[1,2-alindol-6-one structure that have 5-HT receptor affinity and modulate 5-HT activity. Hence, Groups I-XIII claims 1-4 and 14 are directed to the isoindolo[1,2-alindol-6-one compounds. Group XIV (claims 5-13 and 15-18) is drawn to methods of using the isoindolo[1,2-alindol-6-one compounds. Group XV (claims 19-20) is drawn to processes for making the isoindolo[1,2-alindol-6-one compounds. Group XVII (claim 21) is drawn to intermediates in the synthesis of the isoindolo[1,2-alindol-6-one compounds. Group XVII (claim 22) is drawn to a process for making intermediates in the synthesis of the isoindolo[1,2-alindol-6-one compounds. Accordingly, the isoindolo[1,2-alindol-6-one core structure is a technical feature of a group of compounds having a common utility (5-HT receptor affinity and modulation of 5-HT

activity) that defines a contribution which each of the claimed inventions, considered as whole, makes over the prior art, as set forth in PCT Rule 13.2.

Finally, during the international phase of the present application, the International Search Authority and the International Preliminary Examining Authority for the application, which included claims 1-22 that were identical to claims 1-22 of the present application, were found to possess unity of invention despite the fact that claim 1 was (erroneously) not found to be free of the prior art.

For all the reasons set forth above, Applicants respectfully request that the restriction requirement be withdrawn and all claims be examined together.

This request is not an admission that the inventions of exemplary Groups I through XVII identified by the Examiner are not independent or patentably distinct. Applicants believe, in fact, that the Group I through XVII claims are patentable over each other. This, however, is not a basis to restrict the claims, as they all share the technical relationship of the novelty of the isoindolo[1,2-a]indol-6-one core.

The present claims are believed to be in condition for allowance. An early and favorable action on the merits of the application is earnestly requested.

Dated: April 5, 2007

Respectfully submitted,

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EXHIBIT A

driving the marking device and having a supporting surface for the securing disc element. Unity exists between claims 1 and 2.

10.35 Example 15

Claim 1: Compound A.

Claim 2: An insecticide composition comprising compound A and a carrier,

Unity exists between claims 1 and 2. The special technical feature common to all the claims is compound A.

10.36 Example 16

Claim 1: An insecticide composition comprising compound A (consisting of a₁, a₂...)
and a carrier.

Claim 2: Compound a₁.

All compounds A are not claimed in the product claim 2 for reasons of lack of novelty of some of them for instance.

There is nevertheless still unity between the subject matter of claims 1 and 2 provided at has the insecticidal activity that is also the special technical feature for compound A in claim 1.

10.37 Example 17

Claim 1: A chair with a lifting mechanism.

Claim 2: A chair with a mechanical screw lifting mechanism.

Claim 3: A chair with a hydraulic lifting mechanism.

Unity exists between claims 1-3. The special technical feature common to all the claims is the litting mechanism. However, if any lifting mechanism is known in the art, unity would be lacking because there would not be a special technical feature common to all the claims.

Markush Practice

10.38 Example 18: Common Structure

Claim 1: A compound of the formula:

$$R^3 - R^1$$

wherein R^l is selected from the group consisting of phenyl, pyridyl, thiazolyl, triazinyl, alkylthio, alkoxy, and methyl; R^l - R^l are methyl, benzyl, or phenyl. The compounds are useful as pharmaceuticals for the purpose of enhancing the capacity of the blood to absorb oxygen.

In this case the indolyl moiety is the significant structural element that is shared by all of the alternatives. Since all the claimed compounds are alleged to possess the same utility, unity is present.

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10.39 Example 19: common structure:

Claim 1: A compound of the formula:

wherein R_t is selected from the group consisting of phenyl, pyridyl, thiazolyl, triastnyl, alkylthio, alkony, and methyl. It is selected from the group consisting of oxygen (O), sulfur (S), intino (NH), and methylene (CHZ_2) .

The compounds are alleged to be useful as pharmaceuticals for relieving lower back pain.

In this particular case the iminothicether group -N=C-SCH3 linked to a six atom ring is the significant structural element which is shared by all the alternatives. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.40 Example 20: Common Structure

Claim 1: A compound of the formula:

wherein R^I is methyl or phenyl, X and Z are selected from oxygen (0) and sulfur (8)

The compounds are useful as pharmaceuticals and contain the 1,3-thiazolyl substituent which provides greater penetrability of mannalian itssue which makes the compounds useful as relievers for headaches and as topical anti-inflammatory agents.

All compounds share a common chemical structure, the thiazole ring and the six atom heterocyclic compound bound to an imino group, which occupy a large portion of their structure. Thus, since all the claimed compounds are alleged to possess the same use, unity would be present.

10.41 Example 21: Common Structure

 $1 \le \ell \le 10$

 $200 \ge n + m \ge 100$

$$X$$
: H $CH_2O Or$ Or CH_2O-

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All of the above copolymers have in common a thermal degradation resistance property, due to the reduced number of free COOH radicals by esterification with X of the end COOH radicals which cause thermal degradation.

The chemical structures of the alternatives are considered to be technically closely interrelated to one another. A grouping in one claim is therefore allowed.

10.42 Example 22: Common Structure:

$$X:$$
 H $-CH_2O-$ or CH_2 $-CH_2O-$

The compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with $\textcircled{H}-CH_{2}O$ - has a thermal degradation resistant property, due to the reduced number of free COOH radicals which cause thermal degradation. In contrast, the compound obtained by esterifying the end COOH radical of known polyhexamethyleneterephthalate with a vinyl compound containing a $CH_1 = CH - O$ - CH_2O - molety serves as a raw material for a setting resin when mixed with unsaturated monomer and curved (addition reaction).

All esters covered by the claim do not have a property or activity in common. For example, the product obtained through esterification with the "CH₂ = CH" vinyl compound does not have a thermal degradation resistant property. The grouping in a single application is not allowed.

10.43 Example 23: No Common Structure

Claim I: A herbicidal composition consisting essentially of an effective amount of the mixture of A.2 4-DQ. Archichro-phenoxy acetic acidy and B.a second herbicide selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloracetate, dichloropropionic acid, 3-amino-2,3-dichloroberacio acid, diphenamid (aminde), ioxyni (hirrlie), dinoseb (phenol), trifluralin (dimiroaniline), EPTC (thiocarbamate), and stmazine (triazine) along with an inert carrier or diluent.

The different components under B must be members of a recognized class of compounds. Consequently in the present case a unity objection would be raised because the members of B are not recognized as a class of compounds, but, in fact, represent a plurality of classes which may be identified as follows:

(a) inorganic salts:

copper sulfate sodium chlorate

ammonium sulfamate

(b) organic salts and carboxylic acids:

sodium trichloroacetate

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dichloropropionic acid

3-amino-2.5-dichlorobenzoic acid

(c) amides:

diphenamid

(d) nitriles:

ioxynil

(e) phenols:

dinoseb

(f) amines:

.....

trifluralin

heterocyclic:

simazine

10.44 Example 24

Claim 1: A pharmaceutical compound of the formula:

$$A-B-C-D-E$$

wherein:

A is selected from C₁-C₁₀ alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C₂-C₇ heterocycle having 1-3 heteroatoms selected from O and N:

B is selected from C_1 - C_6 alkyl or alkenyl or alkynyl, amino, sulfaxy, C_3 - C_8 ether or thioether:

C is selected from C₃-C₈ saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C₁-C₈ carboxylic acid ester or amide; and

E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl.

From the above formula no significant structural element can be readily ascertained and thus no special technical feature can be determined. Lack of unity exists between all of the various combinations. The first claimed invention would be considered to encompass the first mentioned structure for each variable, that is, A is C, alkyl, B is C, alkyl, C is a C, saturated heterocycle having one O heteroatom, D is C, alkyl, and E as substituted phenyl.

10.45 Example 25

Claim 1: Catalyst for vapor phase oxidation of hydrocarbons, which consists of (X) or (X+a).

In this example (X) oxidizes RCH3 into RCH2OH and (X+a) oxidizes RCH3 further into RCOOH.

Both catalysts share a common component and a common activity as oxidation catalyst for RCH3. With (X+a) the oxidation is more complete and goes until the carboxylic acid is formed but the activity still remains the same.

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A Markush grouping is acceptable in this case.

Intermediate/Final Product

10.46 Example 26

Claim 1:

$$R_2$$
 R_3

(intermediate)

Claim 2:

(final product)

The chemical structures of the intermediate and final product are technically closely interrelated. The essential structural element incorporated into the final product is:

Therefore, unity exists between claims 1 and 2.